



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,591	12/05/2001	Katherine S. Bowdish	1087-3	3521

7590

07/14/2005

Mark Farber  
Alexion Pharmaceuticals, Inc.  
352 Knotter Drive  
Cheshire, CT 06410

EXAMINER

LAMBERTSON, DAVID A

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/006,591

Applicant(s)

BOWDISH ET AL

Examiner

David A. Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,23,24,26-37,73,74 and 85-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23,24,26-37 and 74 is/are allowed.
- 6) ☒ Claim(s) 1-6,73,85-87,90-92,95 and 96 is/are rejected.
- 7) ☒ Claim(s) 88,89,93 and 94 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 26, 2004 has been entered.

New claims 85-96 have been added. Claims 1-6, 23, 24, 26-37, 73, 74 and 85-96 are now pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 26, 2004, that is not addressed in this action has been withdrawn.

***Response to Arguments***

Applicant's arguments with respect to the rejection of claims 1-6, 23-32, 37, 73 and 74 have been considered but are moot in view of the new ground(s) of rejection, which are necessitated by amendment of the claims.

It is noted that on page 9, the third paragraph of Applicant's response, that Applicant indicates the Examiner "suggested" the use of the term "polypeptide encoding portion of a nucleic acid." At no time did the Examiner indicate or suggest that this language would be remedial and lead to the allowance of claims. Rather, in the Advisory Action mailed October 15, 2004, the Examiner merely indicated that Applicant was arguing that the terms used in their claims were equivalent to a "polypeptide encoding

Art Unit: 1636

portion of a nucleic acid," whereas the term "nucleic acid encoding a polypeptide" was actually much broader in scope than what was being argued.

### ***Drawings***

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings contain informal handwritten notations. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following rejection is based upon the following interpretation of the term "mRNA encoding at least a portion of an antibody," or variations thereof (i.e., framework or constant regions) used throughout claims 4, 85-87 and 92. The term "mRNA encoding at least a portion of an antibody" is very broad in scope because a single amino acid residue can represent a "portion of an antibody." Since all mRNA encode at least a single amino acid, all mRNA are capable of encoding "at least a portion of an antibody." Thus, any primer sequence or collar sequence that is capable of annealing to a

Art Unit: 1636

polypeptide encoding portion of an mRNA (or other nucleic acid) is also capable of annealing to an "mRNA encoding at least a portion of an antibody," by the broadest reasonable interpretation of the term.

Claims 1-6, 73, 85-87, 90-92, 95 and 96 rejected under 35 U.S.C. 102(b) as being anticipated by Kohno *et al.* (*Gene* 188: 175-181, 1997; see entire document; henceforth Kohno). The sequence of the *S. cerevisiae* *HIS5* gene (obtained from the Saccharomyces Genome Database (SGD)) is provided for the sole purpose of demonstrating both the distance between and the existence of restriction sites between the "primer" and "collar" sequences.

Kohno teaches a plasmid construct in Figure 1B that meets the limitations of the instantly rejected claims. Specifically, the plasmid of Figure 1B has a 5' "primer" sequence capable of binding to a first portion of a nucleic acid encoding the polypeptide known as Rad52. Kohno also teaches a 3' "collar" sequence that is capable of binding to a second portion of a nucleic acid sequence encoding Rad52, wherein the "primer" and "collar" sequences are separated by at least 20 nucleotides; this is evident from the presence of the *HIS5* gene (1158 nucleotides long; see for example the *HIS5* gene sequence from the SGD) between the "primer" and "collar" sequences. Importantly, the *HIS5* gene (which is located between the "primer" and "collar" sequences) contains numerous restriction sites (see for example the *HIS5* gene sequences from SGD).

***Allowable Subject Matter***

Claims 23, 24, 26-37 and 74 are allowed.

Art Unit: 1636

Claims 88, 89, 93 and 94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson  
AU 1636



JAMES KETTER  
PRIMARY EXAMINER